

Equivalent of Form PTO/506a (2-03)

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/502,403
				Filing Date	§ 371(c) Date: June 20, 2005
				First Named Inventor	LARA OCHOA, José Manuel Francisco
				Art Unit	1611
				Examiner Name	Rae, Charlesworth E.
Sheet	1	of	1	Attorney Docket Number	2099.0090000/PAJ/LMB

U.S. PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (If Known)			
/TL/	US1	3,072,527	01-08-1963	Cohen	
	US2	5,416,105	05-16-1995	Sato <i>et al.</i>	
	US3	5,955,106	09-21-1999	Moeckel <i>et al.</i>	
	US4	6,011,049	01-04-2000	Whitcomb	
	US5	6,031,004	02-29-2000	Timmins <i>et al.</i>	
	US6	6,303,146 B1	10-16-2001	Bonhomme <i>et al.</i>	
	US7	6,348,469 B1	02-19-2002	Seth	
	US8	6,499,984 B1	12-31-2002	Ghebre-Sellassie <i>et al.</i>	
	US9	6,682,759 B2	01-27-2004	Lim <i>et al.</i>	
	US10	6,890,957 B2	05-10-2005	Chandran <i>et al.</i>	
/TL/	US11	2003/0187074 A1	10-02-2003	Hussain <i>et al.</i>	
	US12	2004/0219212 A1	11-04-2004	Castan <i>et al.</i>	
	US13	2007/0264331 A1	11-15-2007	Regalado <i>et al.</i>	

FOREIGN PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ² Number ³ Kind Code ⁴ (If Known)			T ⁶
/TL/	FP1	WO 97/17975 A1	05-22-1997	Istituto Gentili S.P.A.	
	FP2	WO 00/40233 A1	07-13-2000	Hexal AG	Abs ISR
	FP3	WO 01/32158 A2	05-10-2001	Bristol-Myers Squibb Company	
	FP4	WO 03/061643 A1	07-31-2003	Laboratorios Silanes, S.A. de C.V.	Abs
/TL/	FP5	WO 2004/045622 A1	06-03-2004	Ranbaxy Laboratories Limited	

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Examiner Signature	/Trevor Love/	Date Considered	03/11/2010
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Equivalent of Form PTO/SB/08b (2-09)

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/502,403		
		Filing Date	§ 371(c) Date: June 20, 2005		
		First Named Inventor	LARA OCHOA, José Manuel Francisco		
		Art Unit	1611		
		Examiner Name	Rae, Charlesworth E.		
Sheet	1	of	3	Attorney Docket Number	2099.0090000/PAJ/LMB

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
/TL/	NPL1	ABBINK, E.J., <i>et al.</i> , "Vascular effects of glibenclamide vs. glimepiride and metformin in Type 2 diabetic patients," <i>Diabet. Med.</i> 19:136-143, Blackwell Science (February 2002)	
	NPL2	BRESSLER, R., and JOHNSON, D.G., "Pharmacological Regulation of Blood Glucose Levels in Non-Insulin-Dependent Diabetes Mellitus," <i>Arch. Intern. Med.</i> 157:836-848, American Medical Association (1997)	
	NPL3	CEFALU, W.T., <i>et al.</i> , "Insulin Sensitivity is Improved After Glipizide GITS Mono-Therapy and in Combination with Metformin," <i>Diabetologia</i> 39:A231, Springer Verlag (1996)	
	NPL4	CEFALU, W.T., <i>et al.</i> , "Combination Glipizide GITS/Metformin Normalizes Glucose and Improves Insulin Sensitivity in Hyperinsulinemic Moderately Well Controlled NIDDM," <i>Diabetes</i> 45:201A, American Diabetes Association (1996)	
	NPL5	CHARPENTIER, G., <i>et al.</i> , "Improved glycaemic control by addition of glimepiride to metformin monotherapy in Type 2 diabetic patients," <i>Diabet. Med.</i> 18:828-834, Blackwell Science (October 2001)	
	NPL6	CROUSE III, J.R., <i>et al.</i> , "Effects of Combination Glipizide GITS/Metformin Treatment on Oxidizability of LDL in Non-Insulin Dependent Diabetes Mellitus," <i>Circulation</i> 94:1-508, Lippincott Williams & Wilkins (1996)	
	NPL7	DAGOGO-JACK, S., and SANTIAGO, J.V., "Pathophysiology of Type 2 Diabetes and Modes of Action of Therapeutic Interventions," <i>Arch. Intern. Med.</i> 157:1802-1817, American Medical Association (1997)	
	NPL8	DEFRONZO, R.A., "Pharmacologic Therapy for Type 2 Diabetes Mellitus," <i>Ann. Intern. Med.</i> 131:281-303, American College of Physicians (1999)	
↓	NPL9	DEFRONZO, R.A., <i>et al.</i> , "Efficacy of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>N. Engl. J. Med.</i> 333:541-549, Massachusetts Medical Society (1995)	
	/TL/ NPL10	GARBER, A.J., <i>et al.</i> , "Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-controlled, Dose-Response Trial," <i>Am. J. Med.</i> 102:491-497, Excerpta Medica, Inc. (1997)	

Examiner Signature	/Trevor Love/	Date Considered	03/11/2010
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Equivalent of Form PTO/SB/08b (2-09)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/502,403
		Filing Date	§ 371(c) Date: June 20, 2005
		First Named Inventor	LARA OCHOA, José Manuel Francisco
		Art Unit	1611
		Examiner Name	Rae, Charlesworth E.
		Attorney Docket Number	2099.0090000/PAJ/LMB
Sheet	2	of	3

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²	
 /TL/	NPL11	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Eficacia y seguridad de la terapia hipoglucemiante oral combinada de glimepirida más metformina en una sola forma farmacéutica en pacientes con diabetes mellitus tipo 2 y falla secundaria a monoterapia con glibenclámda," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)	✓	
	NPL12	English Language Translation of GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy and safety of glimepiride plus metformin in a single presentation, as combined therapy, in patients with type 2 diabetes mellitus and secondary failure to glibenclamide, as monotherapy," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)		
	NPL13	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy of glimepiride/metformin combination versus glibenclamide/metformin in patients with uncontrolled type 2 diabetes mellitus," <i>J. Diabetes Complicat.</i> , Elsevier Science Publishing Company, 4 pages, Article in Press, uncorrected proof (September 2008)		
	NPL14	GOMIS, R., <i>et al.</i> , "Appropriate Timing of Glimepiride Administration in Patients with Type 2 Diabetes Mellitus," <i>Endocrine</i> 13:117-121, Endocrine Society (2000)		
	NPL15	HERMANN, L.S., <i>et al.</i> , "Therapeutic Comparison of Metformin and Sulfonylurea, Alone and in Various Combinations," <i>Diabetes Care</i> 17:1100-1109, American Diabetes Association (1994)		
	NPL16	HIGGINBOTHAM, L. and MARTIN, F.I.R., "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics," <i>Med. J. Aust.</i> 2:154-156, Australian Medical Publishing Company Limited (1979)		
	NPL17	HOLSTEIN, A., <i>et al.</i> , "Lower Incidence of Severe Hypoglycaemia in Type 2 Diabetic Patients Treated with Glimepiride Versus Glibenclamide," <i>Diabetologia</i> 43:A 40, Springer Verlag (2000)		
	NPL18	MÜLLER, G., <i>et al.</i> , "Differential interaction of glimepiride and glibenclamide with the β -cell sulfonylurea receptor," <i>Biochim. Biophys. Acta</i> 1191:267-277, Elsevier Pub. Co. (1994)		
	NPL19	ROSENSTOCK, J., <i>et al.</i> , "Glimepiride, a New Once-Daily Sulfonylurea," <i>Diabetes Care</i> 19:1194-1199, American Diabetes Association (1996)		
	/TL/	NPL20	SATO, J., <i>et al.</i> , "Comparison between effects of glimepiride and glibenclamide on <i>in vivo</i> insulin action," in <i>Proceedings of the Fourth International Symposium on Treatment of Diabetes Mellitus, Nagoya, 26-27 October 1993</i> , Sakamoto, N., <i>et al.</i> , eds., Excerpta Medica, Amsterdam, Netherlands, pp. 341-348 (1994)	
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Equivalent of Form PTO/SB/085 (2-09)

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		Application Number	10/502,403		
		Filing Date	§ 371(c) Date: June 20, 2005		
		First Named Inventor	LARA OCHOA, José Manuel Francisco		
		Art Unit	1611		
		Examiner Name	Rae, Charlesworth E.		
Sheet	3	of	3	Attorney Docket Number	2099.0090000/PAJ/LMB

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/TL/	NPL21	SCHEEN, A.J., and LEFÈBVRE, P.J., "Oral Antidiabetic Agents. A Guide to Selection," <i>Drugs</i> 55:225-236, ADIS Press (1998)	
	NPL22	SIFTON, D., ed., "Anzemet® Injection," in <i>Physicians Desk Reference, 54th Ed.</i> , Medical Economics Company, Montvale, NJ, pp. 1349-1352 (2000)	
	NPL23	SONNENBERG, G.E., et al., "Short-Term Comparison of Once- Versus Twice-Daily Administration of Glimepiride in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>Ann. Pharmacother.</i> 31:671-676, Harvey Whitney Books Company (1997)	
	NPL24	VIGNERI, R., et al., "Treatment of NIDDM Patients with Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide," <i>Diabete. Metab.</i> 17:232-234, Masson (1991)	
	NPL25	International Search Report for International Application No. PCT/MX02/00003, mailed on January 30, 2003, European Patent Office, Rijswijk, Netherlands	
	NPL26	International Preliminary Examination Report for International Application No. PCT/MX02/00003, completed on April 28, 2004, European Patent Office, Munich, Germany	
V /TL/	NPL27	SHIMPLI, R.D., et al., "Comparison of effect of metformin in combination with glimepiride and glibenclamide on glycaemic control in patient with type 2 diabetes mellitus," <i>Int. J. PharmTech Res.</i> 1:50-61, Sphinx Knowledge House (January-March 2009)	

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